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# THE UNITED STATES OF AMERICA

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July 11, 2000

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APPLICATION NUMBER: 60/152,653

FILING DATE: September 07, 1999

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**PROVISIONAL APPLICATION COVER SHEET**

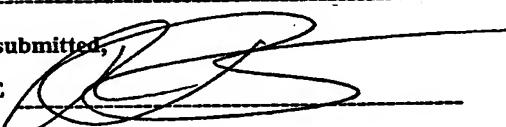
This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (b)(2).

Docket Number	P99;1905		Type a plus sign (+) inside this box →	+	
<b>INVENTOR(s)/APPLICANT(s)</b>					
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)		
Young Russell	Linda Terry	A.	St. Joseph, Missouri deceased		
<b>TITLE OF THE INVENTION (280 characters max)</b>					
<b>METHOD FOR IMPROVING THE SKIN AND COAT OF PETS</b>					
<b>CORRESPONDENCE ADDRESS</b>					
<b>HILL &amp; SIMPSON</b> 233 South Wacker Drive, 85th Floor Sears Tower Chicago					
STATE	Illinois	ZIP CODE	60606	COUNTRY	USA
<b>ENCLOSED APPLICATION PARTS (check all that apply)</b>					
<input checked="" type="checkbox"/> Specification	Number of Pages	13	<input type="checkbox"/> Small Entity Statement		
<input type="checkbox"/> Drawing(s)	Number of Sheets		<input type="checkbox"/> Other (specify)		
<b>METHOD OF PAYMENT (check one)</b>					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the Provisional filing fees <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number: 08-2290					<b>PROVISIONAL FILING FEE AMOUNT (\$)</b>  <b>\$150.00</b>

This invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

- No.  
 Yes, the name of the U.S. Government agency and the Government contract number are \_\_\_\_\_

Respectfully submitted,

SIGNATURE 

Date 9-7-99

TYPED or PRINTED NAME Robert M. Barrett

REGISTRATION NO. (if appropriate) 30,142

- Additional inventors are being named on separately numbered sheets attached here to

### **PROVISIONAL APPLICATION FILING ONLY**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Young et al.

ATTY. DOCKET NO.: P99,1905

SERIAL NO: Unknown

FILED: Herewith

INVENTION: "METHOD FOR IMPROVING THE SKIN AND COAT OF PETS"

Assistant Commissioner for Patents

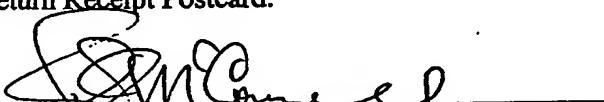
Washington, D.C. 20231

CERTIFICATE OF MAILING BY EXPRESS MAIL

Sir:

I hereby certify that the following documents relating to the above-identified application were deposited in the United States Postal Service Express Mail "Post Office to Addressee" on September 7, 1999:

1. Provisional Application Cover Sheet (in duplicate);
2. Specification (13 pages);
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September 7, 1999

Express Mail Label No. EL 345 371 115 US

NO6645

Patent Application

Title: Method for improving the skin and coat of pets

Inventors: T. Russell (deceased)  
L. Young

Field of the invention

This invention relates to a method of improving or maintaining the condition of the skin and coat of a pet; especially dog and cat pets.

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Background of the invention

A healthy skin and coat is generally considered to be indicative of a healthy pet; and *vice versa*. For this reason, skin and coat problems are one of the 10 primary causes for pet owners to take their pets to veterinarians. These problems may include dryness of the skin, skin flaking, itchiness, skin lesions, dull coat, and the like.

Much can be done to maintain or improve the condition of a pet's skin and 15 coat by feeding the pet a complete and balanced food. This provides the pet with all the essential nutrients and minerals needed to maintain the skin and coat of the pet. However, in view of the many agents in the environment that may damage a pet's skin and coat, feeding the pet a complete and balanced food may not always be sufficient. Therefore many supplements are commercially 20 available for feeding to pets for improving the skin and coat of the pets. These supplements are often of questionable efficacy.

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Zinc and linoleic acid are believed to improve the skin and coat of pets. 25 Therefore it has been suggested to include both zinc and linoleic acid in pet foods in excess of the pets requirements. This approach is described in International Patent Application No WO 98/56263. However, the levels of zinc required are in excess of those permitted in pet foods in certain markets. Also, high levels of linoleic acid are believed by some veterinarians to be pro-inflammatory.

Therefore there remains a need for a method of improving or maintaining the skin and coat of pets.

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Summary of the invention

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Accordingly, in one aspect, this invention provides a method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.

It has been surprisingly discovered that administering to a pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet improves, or at least maintains, the condition of the skin and coat of the pet. Without wishing to be bound by theory, it is believed that, amongst other mechanisms, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet produces nutrients and/or increases the absorption of nutrients which are responsible for the improvement or maintenance of the condition of the skin and coat of the pet. Further, increasing the concentrations of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet may promote a better microflora balance on the skin of the pet.

In another aspect, this invention provides a method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritional agent which increases the digestion of nutrients in the gastro-intestinal tract of the pet.

In a further aspect, this invention provides a method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritional agent which improves the microflora balance on the skin of the pet.

Preferably the nutritional agent is administered to the pet in the form of a complete and nutritionally balanced pet food.

The pet food may contain a source of long chain fatty acids, such as linoleic acid, and/or a source of zinc.

Preferably the method improves or maintains the shininess and softness of the coat of a pet.

The nutritional agent may be a prebiotic or a probiotic micro-organism.

In this specification:-

"Prebiotic" means a substance or compound which is fermented by the intestinal flora of the pet and hence promotes the growth or development of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet at the expense of pathogenic bacteria. The result of this fermentation is a release of fatty acids, in particular short-chain fatty acids in the colon. This has the effect of reducing the pH value in the colon.

"Probiotic micro-organism" means a micro-organism which beneficially affects a host by improving its intestinal microbial balance (Fuller, R; 1989; J Applied Bacteriology, 66: 365-378). In general, probiotic micro-organisms

produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as *Clostridium perfringens* and *Helicobacter pylori*.

Detailed description of the presently preferred embodiments of the invention.

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This invention is based upon the discovery that the condition of the skin and coat of a pet may be improved, or at least maintained, by administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet; and/or increases the digestion of nutrients in the

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gastro-intestinal tract of the pet.

The nutritional agent may be a prebiotic, or a probiotic micro-organism. Further, both prebiotic fibers and probiotic micro-organisms may be administered to the pet.

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Suitable prebiotics include oligosaccharides, such as inulin and its hydrolysis products commonly known as fructooligosaccharides, galacto-oligosaccharides, xylo-oligosaccharides or oligo derivatives of starch.

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The prebiotics may be provided in any suitable form. For example, the prebiotic may be provided in the form of plant material which contains the fiber. Suitable plant materials includes asparagus, artichokes, onions, wheat or chicory, or residues of these plant materials. Alternatively, the prebiotic fiber may be provided as an inulin extract. Extracts from chicory are particularly suitable. Suitable inulin extracts may be obtained from Orafti SA of Tirlmont 3300, Belgium under the trade mark "Raftiline". For example, the inulin may be provided in the form of Raftiline®ST which is a fine white powder which contains about 90 to about 94% by weight of inulin, up to about 4% by weight of glucose and fructose, and about 4 to 9% by weight of sucrose. Alternatively, the fiber may be in the form of a fructooligosaccharide such as obtained from Orafti SA of Tirlmont 3300, Belgium under the trade mark "Raftilose". For example, the inulin may be provided in the form of Raftilose®P95. Otherwise, the fructooligosaccharides may be obtained by hydrolyzing inulin, by enzymatic methods, or by using micro-organisms.

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The probiotic micro-organism may be selected from one or more micro-organisms suitable for animal consumption and which is able to improve the microbial balance in the human or animal intestine.

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Examples of suitable probiotic micro-organisms include yeasts such as *Saccharomyces*, *Debaromyces*, *Candida*, *Pichia* and *Torulopsis*, moulds such as

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Aspergillus, Rhizopus, Mucor, and Penicillium and Torulopsis and bacteria such as the genera Bifidobacterium, Bacteroides, Clostridium, Fusobacterium, Melissococcus, Propionibacterium, Streptococcus, Enterococcus, Lactococcus, Staphylococcus, Pepto-strepococcus, Bacillus, Pediococcus, Micrococcus, Leuconostoc, Weissella, Aerococcus, Oenococcus and Lactobacillus. Specific examples of suitable probiotic micro-organisms are: Saccharomyces cereviseae, Bacillus coagulans, Bacillus licheniformis, Bacillus subtilis, Bifidobacterium bifidum, Bifidobacterium infantis, Bifidobacterium longum, Enterococcus faecium, Enterococcus faecalis, Lactobacillus acidophilus, Lactobacillus alimentarius, Lactobacillus casei subsp. casei, Lactobacillus casei Shirota, Lactobacillus curvatus, Lactobacillus delbrückii subsp. lactis, Lactobacillus farcinimimus, Lactobacillus gasseri, Lactobacillus helveticus, Lactobacillus johnsonii, Lactobacillus reuteri, Lactobacillus rhamnosus (Lactobacillus GG), Lactobacillus sake, Lactococcus lactis, Micrococcus varians, Pediococcus acidilactici, Pediococcus pentosaceus, Pediococcus acidilactici, Pediococcus halophilus, Streptococcus faecalis, Streptococcus thermophilus, Staphylococcus carnosus, and Staphylococcus xylosus. The probiotic micro-organisms may be in powdered, dried form; especially in spore form for micro-organisms which form spores. Further, if desired, the probiotic micro-organism may be encapsulated to further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix.

The nutritional agent may be administered to the pet as a supplement to the pet's normal diet or as a component of a nutritionally complete pet food. It is preferred to include the nutritional agent in a nutritionally complete pet food.

The nutritionally complete pet food may be in any suitable form; for example in dried form, semi-moist form and wet form. These pet foods may be produced as is conventional. Apart from the nutritional agent, these pet foods may include any one or more of a starch source, a protein source and lipid source. Suitable starch sources are, for example, grains and legumes such as corn, rice, wheat, barley, oats, soy, and mixtures of these. Suitable protein sources may be selected from any suitable animal or vegetable protein source; for example meat and meal, poultry meal, fish meal, soy protein concentrates, milk proteins, gluten, and the like. Suitable lipid sources include meats, animal fats and vegetable fats. The choice of the starch, protein and lipid sources will be largely determined by the nutritional needs of the animal, palatability considerations, and the type of product produced. Further, various other

ingredients, for example, sugar, salt, spices, seasonings, vitamins, minerals, flavoring agents, fats and the like may also be incorporated into dried food as desired.

For dried pet foods a suitable process is extrusion cooking, although baking and other suitable processes may be used. When extrusion cooked, the dried pet food is usually provided in the form of a kibble. If a prebiotic is used, the prebiotic may be admixed with the other ingredients of the dried pet food prior to processing. A suitable process is described in European patent application No 0850569; the disclosure of which is incorporated by reference. If a probiotic micro-organism is used, the organism is best coated onto or filled into the dried pet food. A suitable process is described in European patent application No 0862863; the disclosure of which is incorporated by reference.

For wet foods, the processes described in US patents 4,781,939 and 5,132,137 may be used to produce simulated meat products. The disclosures of these patents are incorporated by reference. Other procedures for producing chunk type products may also be used; for example cooking in a steam oven. Alternatively, loaf type products may be produced by emulsifying a suitable meat material to produce a meat emulsion, adding a suitable gelling agent, and heating the meat emulsion prior to filling into cans or other containers.

The maximum level of prebiotic in the pet food is preferably about 20% by weight; especially about 10% by weight. For example, the prebiotic may comprise about 0.1% to about 5% by weight of the pet food. For pet foods which use chicory as the prebiotic, the chicory may be included to comprise about 0.5% to about 10% by weight of the feed mixture, more preferably about 1% to about 5% by weight.

If a probiotic micro-organism is used, the pet food preferably contains about  $10^4$  to about  $10^{10}$  cells of the probiotic micro-organism per gram of the pet food; more preferably about  $10^6$  to about  $10^8$  cells of the probiotic micro-organism per gram. The pet food may contain about 0.5% to about 20% by weight of the mixture of the probiotic micro-organism; preferably about 1% to about 6% by weight; for example about 3% to about 6% by weight.

The pet foods may contain other active agents such as long chain fatty acids and zinc. Suitable long chain fatty acids include alpha-linoleic acid, gamma linoleic acid, linoleic acid, eicosapentanoic acid, and docosahexanoic acid. Fish oils are a suitable source of eicosapentanoic acids and docosahexanoic acid. Borage oil, blackcurrent seed oil and evening primrose oil are suitable sources of

gamma linoleic acid. Safflower oils, sunflower oils, corn oils and soy bean oils are suitable sources of linoleic acid. Zinc may be provided in the form of zinc sulfate and zinc oxide. Further, many ingredients commonly used in pet foods are sources of fatty acids and zinc.

5       The amount of the pet food to be consumed by the pet to obtain a beneficial effect will depend upon the size or the pet, the type of pet, and age of the pet. However an amount of the pet food to provide a daily amount of about 1g to about 100g of prebiotic, or about  $10^6$  to about  $10^{12}$  cells of the probiotic micro-organism, would usually be adequate.

10      Numerous modifications may be made to the embodiments described above without departing from the scope of the invention. Specific examples are now described for further illustration.

Evaluation panel

15      A trained evaluation panel is created to evaluate the skin and coat condition of pets. Parameters to be evaluated by the panelists are visual parameters, touch parameters, and odor parameters. The panel contains 8 panelists. In order to train the panelists, a full sample range of dogs/cats is selected. Several breeds of dogs or several colors of cats are used. All age groups are included for different levels of coat softness. Similarly, non-odorous and odorous animals are included.

20      A vocabulary and glossary are then developed together with the panelists. Different animals are considered and a list of all possible descriptors is generated. This is then reduced to the essential terms pet skin and coat parameters. A glossary is then written to define each descriptor. High and low values for each descriptor on the scale are agreed upon.

25      The panel is then trained. Three cats and three dogs are used. For each attribute, each panelist evaluates the pet on a discrete 9-point scale ranging from "not" to "very". Each panelist's score is compared to the score of the other panelists. The panelists then agree on how attributes should be scored. The panelists then rate three new dogs/cats for the same attribute. The process is repeated until the scores obtained by the panelists are consistent.

30      The trained panelists:

- 35      - agree on the descriptors;  
          - have learnt to use the questionnaire and follow test procedures; and

- are reasonably consistent.

Example 1

5        Four dried pet foods are used in the study. Pet food A is a nutritionally complete dried pet food (ALPO Beefy Dinner). Pet food B is a nutritionally complete dried pet food which is substantially identical to Pet Food A but which contains 3% by weight of linoleic acid. These are the control foods. Pet food 1 is a nutritionally complete dried pet food which is substantially identical to Pet  
10      Food A but which contains 2% by weight of chicory. Pet food 2 is a nutritionally complete dried pet food which is substantially identical to Pet Food 1 but which contains 3% by weight of linoleic acid.

15      A group of 32 dogs are used in the study. The dogs are prefed for 8 weeks using Pet Food A. The dogs are then divided into 4 groups of 8 dogs and fed the following diets for 8 weeks:

Group	Pet Food
A	A
B	B
1	1
2	2

The dogs have free access to water and are fed once a day. The following parameters are determined at 0, 4 weeks, 8 weeks and 12 weeks:-

- 20      - Sebum lipids;  
          - Skin lipids;  
          - Sensory parameters such as skin gloss, scaliness, odor, softness, etc (using the trained panel);  
          - Skin hydration using a corneometer - made in three skin locations (back, below the breast bone, lower abdomen);  
25      - Sebum production using a sebumeter - made in three skin locations (back, below the breast bone, lower abdomen);  
          - Skin pH using a skin pH meter - made in three skin locations (back, below the breast bone, lower abdomen);  
30      - Transepidermal water loss using a tewameter - made in three skin locations (back, below the breast bone, lower abdomen);

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- Skin elasticity using a cutometer- made in three skin locations (back, below the breast bone, lower abdomen);
  - Skin thickness using calipers - made in three skin locations (back, below the breast bone, lower abdomen);
- 5      - Dog/cat allergens using a standard kit;
- Skin and coat odor;
- Skin gloss;
- oxidative stress such as blood superoxide dismutase levels, glutathione peroxidase and total plasma antioxidant levels;
- 10     - serum alpha-1-glycoprotein as an inflammation marker;
- Blood fatty acids.

The dogs are groomed prior to evaluation by the panel and the panel members do not compare notes during the evaluation.

15     The skin and coat condition of all dogs is visually and tactiley good as can be expected of normal, healthy dogs. However, the dogs which are fed Pet Foods 1 and 2 have increased coat shininess, coat softness, skin hydration score, skin elasticity; and blood, skin and sebum linoleic content. Further these dogs have reduced transepidermal water loss, oxidative stress, inflammation and allergic potential. All dogs have substantially the same blood chemistry, skin thickness, skin odor, sebum production and skin pH.

20     Pet Foods 1 and 2 have substantially the same product stability and palatability as Pet Foods A and B.

25     Example 2

30     The procedure of example 1 is repeated with 32 elderly dogs. Four dried pet foods are used in the study. Pet food A is a nutritionally complete dried pet food (ALPO Beefy Dinner). Pet food 3 is a nutritionally complete dried pet food which is substantially identical to Pet Food A but which contains 2% by weight of chicory, 0.5% by weight of alpha-linoleic acid and 3% by weight of linoleic acid. Pet food 4 is a nutritionally complete dried pet food which is substantially identical to Pet Food 3 but which contains 0.5% by weight of eicosapentanoic acid and docosahexanoic acid in place of the alpha-linoleic acid. Pet food 5 is a nutritionally complete dried pet food which is substantially identical to Pet Food 3 but which contains 0.5% by weight of gamma-linoleic acid in place of the alpha-linoleic acid.

The dogs are prefed for 8 weeks using Pet Food A. The dogs are then divided into 4 groups of 8 dogs and fed the following diets for 8 weeks:

Group	Pet Food
A	A
3	3
4	4
5	5

5        The skin and coat condition of all dogs is visually and tactiley good as can be expected of normal, healthy dogs. However, the dogs which are fed Pet Foods 3, 4 and 5 have increased coat shininess, coat softness, skin hydration score, skin elasticity; and blood, skin and sebum linoleic content. Further these dogs have reduced transepidermal water loss, oxidative stress, inflammation and allergenic potential. All dogs have substantially the same blood chemistry, skin thickness, skin odor, sebum production and skin pH. The dogs fed Pet Food 5 have slightly better skin and coat condition than those fed Pet Foods 3 and 4.

10      Pet Foods 3, 4 and 5 have substantially the same product stability and palatability as Pet Food A.

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We Claim

1. A method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
- 5 2. A method according to claim 1 in which the nutritional agent is a component of a nutritionally complete pet food.
- 10 3. A method according to claim 1 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
- 15 4. A method according to claim 3 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
- 5 5. A method according to claim 1 in which the pet food further comprises a long chain fatty acid.
- 20 6. A method according to claim 1 in which the pet food further comprises a zinc source.
- 25 7. A method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritionally complete pet food which contains a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
- 30 8. A method according to claim 7 in which the nutritional agent is selected from the group of prebiotics and probiotic micro-organisms.
9. A method according to claim 8 in which the prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.
- 35 10. A method according to claim 7 in which the pet food contains about 0.1% to about 5% by weight of a prebiotic fiber as the nutritional agent.

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NO6645

11. A method according to claim 7 in which the pet food contains about 10<sup>4</sup> to about 10<sup>10</sup> cells of a probiotic micro-organism per gram of the pet food as the nutritional agent.
- 5           12. A method according to claim 7 in which the pet food further comprises a long chain fatty acid.
- 10          13. A method according to claim 7 in which the pet food further comprises a zinc source.
- 15          14. A method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritional agent which increases the digestion of nutrients in the gastro-intestinal tract of the pet.
- 20          15. A method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritional agent which improves the microflora balance on the skin of the pet.
- 25          16. A method for improving or maintaining shininess and softness of the coat of a pet, the method comprising administering to the pet a nutritional agent which promotes the growth of bifido- and lactic-bacteria in the gastro-intestinal tract of the pet.
- 30          17. A method for improving or maintaining shininess and softness of the coat of a pet, the method comprising administering to the pet a nutritional agent which increases the digestion of nutrients in the gastro-intestinal tract of the pet.
18. A method for improving or maintaining the skin and coat of a pet, the method comprising administering to the pet a nutritionally complete pet food which contains a long chain fatty acid and a prebiotic is selected from the group of inulin, fructooligosaccharides and plant materials which contain inulin and/or fructooligosaccharides.

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NO6645

Abstract of the Disclosure

A method for improving or maintaining the skin and coat of a pet. The pet  
is administered a nutritional agent which promotes the growth of bifido- and  
5 lactic-bacteria in the gastro-intestinal tract of the pet. The nutritional agent may  
be a prebiotic or a probiotic micro-organism, or both.

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